ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A clinical trial to compare mosunetuzumab plus polatuzumab vedotin with rituximab plus gemcitabine plus oxaliplatin in people with relapsed or refractory aggressive non-Hodgkin's lymphoma

A Study Evaluating Efficacy and Safety of Mosunetuzumab in Combination With Polatuzumab Vedotin Compared to Rituximab in Combination With Gemcitabine Plus Oxaliplatin in Participants With Relapsed or Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	13 Countries	NCT05171647 GO43643

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will assess the efficacy and safety of mosunetuzumab in combination with polatuzumab vedotin (M+P) in participants with relapsed or refractory (R/R) diffuse-large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, transformed follicular lymphoma (trFL) and FL Grade 3B (FL3B) in comparison with a commonly used regimen in this participant population, rituximab, gemcitabine and oxaliplatin (R-GemOx).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT05171647 GO43643
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the SUNMO clinical trial work?

This clinical trial is recruiting people who have aggressive non-Hodgkin's lymphoma (NHL), according to specific criteria. In order to take part, patients must have disease that has returned after successful treatment (relapsed) or that has not responded to treatment (refractory).

The purpose of this clinical trial is to compare the effects, good or bad, of mosunetuzumab plus polatuzumab vedotin (called ‘M+P’ in this document) versus rituximab plus gemcitabine plus oxaliplatin (called ‘R-GemOx’ in this document) on patients with aggressive NHL. In this clinical trial, you will get either M+P or R-GemOx.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with aggressive NHL, according to specific criteria. You must have received at least one previous treatment for NHL, after which the cancer did not get better or came back.

If you have certain other medical conditions or have received certain medications or treatments, you may not be able to take part in this clinical trial. If you are pregnant or breastfeeding, or are intending to become pregnant shortly after your last dose of clinical trial treatment, you will not be able to take part in this clinical trial.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly (like tossing a coin) and given either:

- M+P treatment: mosunetuzumab, as an injection under the skin (subcutaneous) once a week for the first three weeks (Cycle 1), then once every three weeks for Cycles

2-8. You will also be given polatuzumab vedotin as an infusion into the vein once every three weeks for Cycles 1-6

OR

- R-GemOx treatment: rituximab, gemcitabine and oxaliplatin, each given as infusions into the vein every two weeks for up to eight cycles.

You will have a 2 in 3 chance (67%) of being placed in the M+P group and a 1 in 3 chance (33%) of being placed in the R-GemOx group.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatments for up to 24 weeks (roughly six months) in the M+P group or for up to 16 weeks (roughly four months) in the R-GemOx group. You will also have some additional tests and procedures, such as blood tests, for research purposes. You are free to stop this treatment at any time. After you have finished your treatment, you will still be seen regularly by the clinical trial doctor every three months for up to two and a half years (from when you started clinical trial treatment). These hospital visits will include checks to see how you have responded to the treatment and checks on any side effects that you may be having.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT05171647